

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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TITLE: SYSTEM FOR THE CONTROL, VERIFICATION AND RECORDING OF THE PERFORMANCE OF A RADIOISOTOPE GENERATOR'S OPERATIONS

REMARKS ON PRELIMINARY AMENDMENT

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

In conjunction with the filing of the present application, and prior to an initial Official Action on this matter, please amend the above-identified application as provided in the attached Marked Up Copy and Substitute Specification.

Please note that the following amendments in the Substitute Specification apply to the attached specification and claims labeled for "U.S. filing". This combined application incorporates the original application and any amendments or annex to the International Application in the proper order, including the correct original and substitute pages, claims and drawing sheets.

In this preliminary amendment, please consider the following remarks in conjunction with the amendments to the above-identified application as follows:

REMARKS

The present Preliminary Amendment has been entered for the purpose of placing the application into a more proper U.S. format. In particular, certain grammatical and idiomatic

inconsistencies have been corrected by amendment to the specification, and the application is corrected for certain typographical errors found in the originally submitted application. No new matter has been added by these amendments. The present application incorporates the original filing including any amendments made in the international filing. There was no amendment in the International Application, and there is no annex to the International Preliminary Examination Report because a Demand for an IPER was not filed.

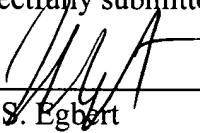
The Claims have been amended so as to conform with U.S. requirements and so as to remove multiple dependent claims. The Abstract has been amended so as to conform to U.S. filing requirements.

Applicant respectfully requests that the present Amendment be entered prior to an initial Official Action on the present application.

7.19.06
Date

Customer No. 24106

Respectfully submitted,


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CLAIMS

We claim:

1. (Currently amended) A system to provide performance control of a radioisotope generator, said system comprising:
 - a radioisotope generator;
 - an electronic sensor of elution;
 - an eluted activity measurement sensor;
 - ~~a device to measure the means for measuring~~ nuclear quality of the eluted radioisotope;
 - an electronic memory with information ~~to the~~ for a user;
 - a communication interface; and
 - an user interface software.
2. (Original) A system according to claim 1, wherein said radioisotope generator is a Mo-99 / Tc-99m generator.
3. (Original) A system according to claim 1, wherein the electronic sensor of elution measures changes in high frequency conductometry.
4. (Currently amended) A system according to claim 1, wherein the eluted activity sensor ~~can~~ be either is comprised of a Geiger Müller tube, a micro ionization chamber or a solid state detector.
5. (Currently amended) A system according to claim 1, wherein the electronic memory with information ~~to the user includes~~ is comprised of Lot No., Generator No., activity, calibration date and expiration dates.

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6. (Original) A system according to claim 1, wherein the communication interface uses one or more of the following ports of a PC: RS232, USB, or parallel port.

7. (Currently amended) A system according to claim 2, wherein the ~~device to measure the nuclear quality of the eluted Tc-99m~~ consists means for measuring is comprised of a radioactivity sensor protected by a 3 mm lead shield.

8. (Currently amended) A system according to claim 1, wherein the electronic sensor of elution measures changes in photon intensity passing through a portion of ~~the~~ elution tubing which is being transparent to ~~these~~ photons.

9. (Currently amended) A system according to claim 1, wherein the electronic sensor of elution measures changes in the electrical impedance of a portion of ~~the~~ elution tubing.

10. (Currently amended) A system according to claim 1, wherein the electronic sensor of elution measures changes in the dielectric capacity of a portion of ~~the~~ elution tubing.

11. (Currently amended) A method to detect and measure passage of elution in a radioisotope generator ~~based on one of the following, said method comprising a step from a group consisting of:~~ using High-frequency conductometry; using Photometry; using Impedanceometry; using Electrical capacitometry; using Emitted radiation detection; and using Magnet-hydrodynamic.

12. (Currently amended) A method according to claim 11, wherein using high frequency conductometry ~~measures the~~ is comprised of measuring changes in the electrical resistance of a portion of ~~the~~ elution tubing of said the generator.

13. (Currently amended) A method according to claim 11, wherein using photometry ~~measures the~~ is comprised of measuring changes in the intensity of a light beam going through a

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translucent portion of the elution tubing ~~by means of~~, a high intensity light emitter being pointed to the translucent portion of the elution tubing, ~~and~~ a phototube/photomultiplier being placed on the ~~an~~ other side of the translucent portion of said elution tubing of said radioisotope generator, ~~and~~ being directly opposite to the light emitter.

14. (Currently amended) A method according to claim 11, wherein using impedanceometry ~~measures the~~ is comprised of measuring changes in the frequency of a free oscillator (~~rod-capacitor~~) ~~by means of~~ or rod-capacitor, a coil surrounding a portion of the elution tubing and a free oscillator being connected to the coil; wherein a frequency counter detects impedance changes of the coil if liquid passes through.

15. (Currently amended) A method according to claim 11, wherein using capacitometry ~~measures the~~ is comprised of measuring changes in the dielectric capacity ~~by means of~~, two electrodes being placed externally on both sides of a portion of the elution tubing, the tubing being non-metallic with an external diameter of not more than 2 mm, ~~the~~ liquid changing ~~the~~ an internal dielectric constant of ~~this~~ a capacitor formed by the electrodes and the tubing, ~~and~~ a capacitometer being connected to ~~these~~ the electrodes measures the measuring changes of the capacity when liquid passes through the tubing.

16. (Currently amended) A method according to claim 11, wherein using emitted radiation detection ~~measures the~~ is comprised of measuring changes in the ~~a~~ radiation field generated by the eluted radioisotope passing through the elution tubing of said radioisotope generator, ~~by means of~~ a properly-shielded-from-other-sources-of-radiation radiation detector being placed against said elution tubing of said radioisotope generator.

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17. (Currently amended) A method according to claim 11, wherein using magnet-hydrodynamic ~~measures the~~ is comprised of changes to the an orthogonal electric field generated by a magnetic field applied to the elution tubing ~~by means of~~, a magnetic field being applied on a portion of the elution tubing, two electrodes orthogonal to the magnetic field measuring a low electric field that is a function of the liquid flow, and when the liquid passes through the tubing, the electric field ~~increases and thereby indicates the~~ increasing and indicating elution.

18. (Currently amended) A method to measure the dryness of a "dry" Mo-99 / Tc-99m generator ~~wherein~~, said method comprising the steps of:

using high frequency conductometry measures the to measure changes in the electrical resistance through ~~the~~ a column ~~by means of~~, electrodes being placed on the IN and on the OUT metal tubing or needles of said the generator.

19. (Currently amended) A method to detect and measure the radionucleidic purity of the Tc-99m as ~~it is~~ eluted from a Mo-99 / Tc-99m generator ~~that measures the,~~ said method comprising the steps of:

measuring changes in the a radiation field generated by ~~the~~ eluted radioisotope passing through ~~the~~ elution tubing of said the radioisotope generator, ~~by means of~~ a second properly-shielded-from-other-sources-of-radiation radiation detector being placed against a 3mm thick lead shield, ~~which is~~ in direct contact with said elution tubing of said radioisotope generator.

20. (Currently amended) A method to transmit the data generated according to ~~the methods in claims 11, 18 and 19~~ Claim 11, further comprising:

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transmitting data to a PC or data processor through a RS232 or USB or a parallel port or any other input-output port of a PC.

21. (Currently amended) A ~~method~~ system according to claim 5, wherein the electronic memory is comprised of a non-volatile memory such as EEPROM, ~~and said~~ the memory, upon connecting ~~the system to the~~ a PC ~~transfers to the program the~~, transferring information stored by ~~the~~ a manufacturer specific to ~~that~~ a particular generator.

22. (Currently amended) An ~~user interface software~~ system according to claim 1, ~~which~~ wherein user interface software is able to process and logs all ~~the~~ data introduced from the generator ~~as known to those skilled in the art~~.

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ABSTRACT OF THE DISCLOSURE

This invention is referred to a digital technetium Tc-99m generator obtained by incorporating devices to allow the control, verification and recording of all the operations performed by the generator. The invention includes a conventional traditional generator Mo-99/Tc-99m, using either a dry or wet column, such as the ones commercially available for use in nuclear medicine; ~~an.~~ The invention also includes an electronic sensor of elution; an eluted activity measurement sensor; and a device to measure the nuclear quality of the eluted Tc-99m; ~~an.~~ There is an electronic memory means with information to for the user regarding: Generator No., Lot No., activity, calibration and expiration dates; ~~a.~~ The invention also includes a communication interface, whether via RS232;, USB, parallel Port or any other input-output port of a PC; and a control, and user interface software.